A Study to Evaluate the Efficacy and Safety of Cevostamab in Prior B Cell Maturation Antigen-Exposed Patients with Relapsed/Refractory Multiple Myeloma

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	92
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-505865-94-00 (CTIS)

Cod. Protocolo
CO43476

Transicionado 2021-006816-10

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Relapsed/Refractory Multiple Myeloma

Título Científico
A Phase I/II, Open-Label, Multi-Cohort Study to Evaluate the Efficacy and Safety of Cevostamab in Prior B Cell Maturation Antigen-Exposed Patients With Relapsed/Refractory Multiple Myeloma

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of cevostamab based on investigator assessed Objective response rate (ORR) To evaluate the safety and tolerability of cevostamab

Variables de Evaluación Primaria

1. ORR, defined as the proportion of participants with an objective response [stringent complete response (sCR), complete response (CR), very good partial response (VGPR), or partial response (PR)], based on investigator-assessed response, according to IMWG criteria
2. Incidence and severity of adverse events, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v5.0 and American Society for Transplantation and Cellular Therapy (ASTCT) for CRS and of immune effector cell associated neurotoxicity syndrome (ICANS) grading

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of cevostamab based on IRC assessed ORR, DOR, CR or better, rate of VGPR or better, OS, PFS, time to first response, time to best response, proportion of participants experiencing a clinically meaningful improvement and time to deterioration assessed by EORTC QLQ-C30 and EORTC QLQ-MY20
To characterize the PK of cevostamab in participants with MM
To evaluate the immune response to cevostamab, potential relationships between cevostamab exposure and pharmacodynamic biomarkers
To make a preliminary assessment of the efficacy of tocilizumab in ameliorating the symptoms of CRS following treatment with cevostamab
To identify biomarkers that may be: - Able to provide evidence of cevostamab activity and to increase the knowledge and understanding of disease biology - Predictive of response to cevostamab - Associated with progression to a more severe disease state, acquired resistance to cevostamab and susceptibility to developing adverse events

Variables de Evaluación Secundaria

1. ORR, defined as the proportion of participants with an objective response based on independent review committee (IRC)-assessed response
2. Duration of response (DOR), defined as the time from the first occurrence of an objective response until the date of disease progression or death from any cause (whichever occurs first), as determined separately by the IRC and the investigator
3. Rate of CR or better, defined as the proportion of participants who achieve a response of sCR or CR, as assessed

separately by IRC and the investigator
4. Rate of VGPR or better, defined as the proportion of participants who achieve a response of VGPR or better, as assessed separately by IRC and the investigator
5. Overall survival (OS), defined as the time from initiation of study treatment to death from any cause
6. Progression-free survival (PFS), defined as the time from initiation of study treatment to the first occurrence of disease progression, relapse, or death from any cause (whichever occurs first), as assessed separately by IRC and the investigator
7. Time to first response (for participants who achieve an objective response), defined as time from initiation of study treatment to first achieving an objective response (separate analyses by IRC and investigator)
8. Time to best response (for participants who achieve an objective response), defined as time from initiation of study treatment to achieving the deepest response (separate analyses by IRC and investigator)
9. Proportion of participants experiencing a clinically meaningful improvement in the fatigue domain of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Core-30 Questionnaire (QLQC-30) and EORTC QLQ-MY20
10. Time to deterioration in the fatigue domain of the EORTC QLQ-C30 and/or disease symptoms domain of the EORTC QLQ-MY20
11. Serum concentration of cevostamab at specified timepoints
12. Pharmacokinetics (PK) parameters of cevostamab, as data allow
13. Prevalence of anti-drug antibodies (ADAs) against cevostamab at baseline and incidence of ADAs against cevostamab during the study
14. CRS outcome following administration of tocilizumab (e.g., time to CRS resolution, doses of tocilizumab administered, relationship between serum concentration or other PK parameters for tocilizumab and pharmacodynamic biomarkers)
15. Relationship between serum concentration or other PK parameters for cevostamab and pharmacodynamic biomarkers, including, but not limited to, cytokine release, T cell number, and T-cell activation state
16. Relationship between biomarkers in blood, bone marrow biopsies and aspirates, and tumor tissue and efficacy, safety, PK, immunogenicity, or other biomarker endpoints

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Documented diagnosis of multiple myeloma (MM) based on standard International Myeloma Working Group (IMWG) criteria
Evidence of progressive disease based on investigators determination of response by IMWG criteria on or after their last dosing regimen
Prior B cell maturation antigen (BCMA) antibody-drug conjugate (ADC) or chimeric antigen receptor T (CAR-T) Cohort: participants who have received a BCMA-targeted CAR-T or ADC therapy and are triple-class relapsed or refractory
Prior BCMA Bispecific Cohort: participants who have received a BCMA-targeting T-cell-dependent bispecific (TDB) antibody and are triple-class relapsed or refractory
Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
Life expectancy is at least 12 weeks

Criterios de Exclusión

Inability to comply with protocol-mandated hospitalization

Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 5 months after the final dose of cevostamab or within 3 months after the last dose of tocilizumab
Prior treatment with cevostamab or another agent with the same target
Prior BCMA ADC or CAR-T Cohort: prior treatment with any T cell dependent bispecific antibody (TDB) antibody including non BCMA targeting TDB
Prior BCMA Bispecific Cohort: treatment with TDB antibody within 12 weeks prior to enrollment in the study
Prior use of any monoclonal antibody (mAb), radioimmunoconjugate, or ADC as anti-cancer therapy within 4 weeks before first study treatment, except for the use of non-myeloma therapy

Calendario

(Última actualización: 25/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
03/08/2022	18/11/2022	01/12/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
31/10/2024	No aportado	No aportado	No aportado	No aportado

Promotor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de la Comunidad Foral de Navarra

C/ Irunlarrea, 3 31008 Pamplona

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Centros

Cerrado (07/03/2025)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

Cerrado (07/03/2025)

CLINICA UNIVERSIDAD DE NAVARRA

Madrid

MADRID

Servicio de Hematología

Activo (18/11/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematología

Cerrado (27/02/2025)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Servicio de Hematología

Activo (01/02/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

Medicamentos

Cevostamab
SOLUTION FOR INFUSION
IV INFUSION

Principios Activos: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L04AC07 - TOCILIZUMAB
Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate the Efficacy and Safety of Cevostamab in Prior B Cell Maturation Antigen-Exposed Patients with Relapsed/Refractory Multiple Myeloma

State	**Type of participants**	**Age Ranges**
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	92
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-505865-94-00 (CTIS)

Protocol Code
CO43476

Transitioned 2021-006816-10

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Relapsed/Refractory Multiple Myeloma

Scientific Title
A Phase I/II, Open-Label, Multi-Cohort Study to Evaluate the Efficacy and Safety of Cevostamab in Prior B Cell Maturation Antigen-Exposed Patients With Relapsed/Refractory Multiple Myeloma

Rationale

Not provided

Main Objective

To evaluate the efficacy of cevostamab based on investigator assessed Objective response rate (ORR) To evaluate the safety and tolerability of cevostamab

Primary Endpoints

1. ORR, defined as the proportion of participants with an objective response [stringent complete response (sCR), complete response (CR), very good partial response (VGPR), or partial response (PR)], based on investigator-assessed response, according to IMWG criteria
2. Incidence and severity of adverse events, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v5.0 and American Society for Transplantation and Cellular Therapy (ASTCT) for CRS and of immune effector cell associated neurotoxicity syndrome (ICANS) grading

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of cevostamab based on IRC assessed ORR, DOR, CR or better, rate of VGPR or better, OS, PFS, time to first response, time to best response, proportion of participants experiencing a clinically meaningful improvement and time to deterioration assessed by EORTC QLQ-C30 and EORTC QLQ-MY20
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Secondary Endpoints

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separately by IRC and the investigator
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16. Relationship between biomarkers in blood, bone marrow biopsies and aspirates, and tumor tissue and efficacy, safety, PK, immunogenicity, or other biomarker endpoints

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Documented diagnosis of multiple myeloma (MM) based on standard International Myeloma Working Group (IMWG) criteria
Evidence of progressive disease based on investigators determination of response by IMWG criteria on or after their last dosing regimen
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Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
Life expectancy is at least 12 weeks

Exclusion criteria

Inability to comply with protocol-mandated hospitalization

Pregnancy or breastfeeding, or intention of becoming pregnant during the study or within 5 months after the final dose of cevostamab or within 3 months after the last dose of tocilizumab
Prior treatment with cevostamab or another agent with the same target
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Calendar

(Last Update: 25/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
03/08/2022	18/11/2022	01/12/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
31/10/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Closed (07/03/2025)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

Closed (07/03/2025)

CLINICA UNIVERSIDAD DE NAVARRA

Madrid

MADRID

Servicio de Hematología

Active (18/11/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematología

Closed (27/02/2025)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Servicio de Hematología

Active (01/02/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

Medication

Cevostamab
SOLUTION FOR INFUSION
IV INFUSION

Active Principles: N/A

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L04AC07 - TOCILIZUMAB
Active Principles: N/A

Experimental

No results